

UNITED STATES DISTRICT COURT
DISTRICT OF VERMONT

JONATHAN A. BLOOM,)	
)	
Plaintiff,)	
v.)	Civil Action No. 5:16-cv-121
)	
SYLVIA BURWELL,)	
Secretary, United States Department)	
of Health and Human Services,)	
)	
Defendant.)	

**PLAINTIFF'S OPPOSITION TO DEFENDANT'S MOTION FOR REMAND
PURSUANT TO 42 U.S.C. §405(g) AND MEMORANDUM OF LAW**

Plaintiff Jonathan Bloom, by his undersigned counsel, files this opposition to Defendant's Motion for Remand Pursuant to the Sixth Sentence of 42 U.S.C. § 405(g) (the "Motion"). Plaintiff submits the following memorandum in support of his opposition to the Motion of the Secretary of the United States Department of Health and Human Services (the "Secretary") because a remand is not supported by either law or fact.

I. INTRODUCTION

Plaintiff Jonathan Bloom, a Medicare beneficiary with Type 1 diabetes, brought this action challenging final decisions by the Medicare Appeals Council ("MAC"), which denied coverage of a transmitter and sensors for his continuous glucose monitor ("CGM"). The MAC denied coverage finding that because:

the CGM does not substitute for the existing means of controlling insulin usage, or measure blood glucose directly, we conclude that it merely provides an added precaution and does not itself service a primary medical purpose. Accordingly, we find no basis to depart from the applicable program guidance, which provides that CGMs assigned with HCPCS codes A9276 through A9278 . . . do not meet the definition of [Durable Medical Equipment ("DME")] because they are precautionary.

The Secretary argues two reasons warrant a remand: (1) it appears the MAC misapplied the Policy Article as a Local Coverage Determination (“LCD”); and (2) aside from a manufacturer’s website that the MAC took judicial notice of, the administrative record does not contain substantive evidence regarding why a CGM is considered precautionary and/or is otherwise outside the Medicare benefit category of DME. *See* Motion at 2 and 3. Thus, the Secretary neither concedes her ultimate decision is wrong,¹ the error in the MAC’s possible reliance on a Policy Article,² nor the deficiency of the administrative record. Rather, the Secretary apparently seeks a remand solely to enable her to better develop her arguments and evidence to deny the CGM claims at issue. The Secretary further argues the remand will be in the interest of judicial economy. The Secretary, however, fails to make the *prima facie* showings necessary for a remand, and a remand will not lead to timely resolution of the case.

The Secretary asks the Court to ignore the fundamental role of the judiciary in ensuring agencies follow their Congressionally mandated processes and procedures and render decisions that are supported by substantial evidence and are not arbitrary and capricious, and suggests that a Medicare beneficiary who repeatedly has exhausted his Medicare administrative remedies endure yet another round of untimely administrative appeals.

II. STATUTORY AND REGULATORY FRAMEWORK

A. Local Coverage Determinations

A Durable Medical Equipment Medicare Administrative Contractor (“DMAC”) may issue an LCD, which indicates when an item will or will not be covered. LCDs are to be based on the strongest available evidence (including peer-reviewed literature, medical societies, the consensus of experts) and developed in consultation with the relevant medical community. *See*

¹ *See* Motion at 3 n.4.

² *See* Motion at 3 (“[P]ortions of the MAC’s decision *may* have involved misapplication of 42 C.F.R. § 1062(a).”) (emphasis added).

Medicare Program Integrity Manual Ch. 13, §13.7.1. If a policy is developed relating to DME, to the extent that it is not clear whether an item is medical equipment, the relevant DMACs are directed to confer with relevant experts. *See* Medicare Benefit Policy Manual (“MBPM”), Ch. 15, §110.1.B.

If a Medicare beneficiary believes an LCD is not supported by substantial evidence, a Medicare beneficiary may file an LCD challenge. The relevant DMAC, NHIC, issued LCD L11530 articulating coverage requirements for glucose monitors and listing the relevant codes for CGM therein. The LCD does not indicate CGM is not covered.

In contrast to LCDs, which communicate coverage determinations, Policy Articles convey coding and payment information. Articles are not developed based on peer-reviewed literature. Contrary to the Secretary’s assertion, “Policy Articles” do not “guide Medicare coverage decisions” (Motion at 6); coverage decisions are required to be developed through the LCD process described. Articles are not entitled to deference as the MAC has recognized. *See, e.g., In the Case of The Rehabilitation Center, Inc.*, M-2012-328 (Medicare Appeals Council, Feb. 24, 2012). DMAC NHIC issued Article A33614, which states CGMs are precautionary and are therefore not covered under the DME benefit.

B. The Medicare Appeals Process

The Medicare statute provides Medicare beneficiaries the right to appeal individual claim denials through the multi-step administrative appeals process. The Medicare beneficiary must first file a request for redetermination to the DMAC that initially denied the claim, then file a request for reconsideration to a Qualified Independent Contractor (“QIC”), and then file a request for an administrative law judge (“ALJ”) hearing. The Center for Medicare and Medicaid Services (“CMS”), the relevant DMAC, and the relevant QIC may participate as parties or

witnesses at the ALJ level. The ALJ conducts a *de novo* review of the claim denial and, pursuant to requirements in the Benefits Improvement and Protections Act of 2000 (“BIPA”) and Medicare regulations, should issue a decision within 90 days of request for review. 42 C.F.R. § 405.1016. The ALJ’s decision constitutes the Secretary’s final decision unless a Medicare beneficiary appeals the decision or the Medicare Appeals Council decides to review the ALJ’s decision on its own motion. If neither CMS, the DMAC, nor QIC participated in the ALJ hearing, the MAC should only review an ALJ’s decision if it contains an error of law. The MAC must conduct a *de novo* review of the ALJ’s decision and render a decision within 90 days of an appeal or Own Motion Review. *See* 42 C.F.R. §§405.1100(a), 405.1108 (a). The MAC’s review is limited to the evidence contained in the record at the ALJ level. 42 C.F.R. §405.1122(a). If the MAC renders a decision, it constitutes the Secretary’s final decision. Although ALJs and the MAC are bound to follow national coverage determinations, neither the ALJ nor the MAC is bound to follow LCDs, although they must give them substantial deference. Neither the ALJ nor MAC decisions are precedential. 74 Fed. Reg. 65296, 65327 (Dec. 9, 2009)³; 68 Fed. Reg. 55634 (Sept. 26, 2003). Only after exhaustion of each of these administrative steps may a Medicare beneficiary seek relief from a District Court from a decision that is arbitrary and capricious and not supported by substantial evidence.

C. Sentence Six Remands

The sixth sentence of 42 C.F.R. §405(g) provides for two types of remands: (1) remands for good cause before the Secretary answers a complaint; and (2) remands upon a showing that there is new evidence which is material and that there is good cause for the failure to incorporate such evidence into the record in the prior proceeding. With respect to first clause sixth sentence

³ “After thorough consideration, DHHS determined that it is neither feasible, not appropriate at this time to confer binding, precedential authority upon decisions of the MAC. . . . [T]he MAC decisions are not given precedential weight.” 74. Fed. Reg. 65296, 65327 (Dec. 9, 2009).

remands, good cause has been found when the Secretary admits the decision was erroneous as a matter of law based on the existing administrative record, and the Secretary desires to apply the correct legal standard. *See Art of Healing Medicine, P.C v. Burwell*, 91 F. Supp. 3d 400, 417 (E.D.N.Y. 2015); *Torres v. Shalala*, 938 F. Supp. 211, 215-218 (S.D.N.Y. 1996); *Fernandez v. Sullivan*, 809 F. Supp. 226, 228-29 (S.D.N.Y. 1992); *Correa v. Sullivan*, 1992 WL 367116 (S.D.N.Y. 1992).⁴

To satisfy the requirements for the second clause sixth sentence remand, a party must show (1) there is new evidence; (2) which may affect the outcome; and (3) there is good cause why it was not introduced below. *See DeYoung v. Shalala*, 1995 WL 579755, at *1 (D. Vt. 1995) (citing *Longey v. Sullivan*, 812 F. Supp. 453 n.3 (D. Vt. 1993)); *see also Shalala v. Schaefer*, 509 U.S. 292, 297 n.2 (1993); *Formica v. Shalala*, 1994 WL 414299, at *2 (D. Conn. Apr. 7, 1994).

III. STATEMENT OF FACTS AND RELATED PROCEEDINGS

A. Dr. Bloom's Exhaustion of Multiple Administrative Proceedings

Dr. Bloom was prescribed a continuous glucose monitor to enable him to control his Type 1 diabetes with hypoglycemic unawareness. A CGM requires monthly sensor supplies. As described below, because Dr. Bloom needs monthly supplies for his CGM, he has taken multiple claims through the Medicare appeal process resulting in numerous decisions that his CGM and supplies are covered under Medicare, and directing the relevant Durable Medical Equipment Medicare Administrative Contractor ("DMAC"), NHIC, to cover and make payment for the same. When Dr. Bloom first submitted his claims for the CGM and related supplies, NHIC

⁴ In her Motion, the Secretary cites cases relating to a fourth sentence remand under 42 C.F.R. §405(g). *See* Motion at 8-9 (citing, e.g., *Rosa v. Callahan*, 168 F.3d 72, 82-83). Sentence four cases are inapposite because the Secretary has not answered the complaint and filed the administrative record and because the record will show Dr. Bloom is entitled to coverage for his CGM and related supplies.

denied the claims citing Local Coverage Determination L11530, which he appealed through the multi-step Medicare administrative appeals process. The first claims Dr. Bloom appealed were for a date of service in June 2010. In October 2011, Dr. Bloom received his first favorable ALJ decision wherein the ALJ found that the CGM system and its supplies were reasonable and medically necessary for Dr. Bloom. When subsequent CGM claims continued to be denied, Dr. Bloom continued to appeal and in September 2012 received a second favorable decision from a different Medicare ALJ for all CGM claims with dates of service between January 2011 and August 2011. Thereafter he received a third favorable decision from a third Medicare ALJ in October 2013 and a fourth favorable decision from a fourth Medicare ALJ in June 2015. In August 2015, the QIC sought the MAC's review of the fourth favorable ALJ decision.⁵ The MAC issued its two unfavorable decisions in November 2015⁶ and February 2016 relating to claims from 2014.

In December 2014, while Dr. Bloom was appealing the individual CGM claims denied, another Medicare beneficiary filed a challenge to NHIC's policy statement that CGMs are precautionary and therefore not covered under the DME benefit. CMS chose not to participate in the LCD challenge process and neither NHIC nor CMS identified a single witness, and certainly not one with medical credentials, willing to testify that CGM was not primarily medical equipment and/or that it is precautionary. Neither CMS nor NHIC submitted a single peer-reviewed publication in support of the policy that CGM is "precautionary." Although the Medicare beneficiary identified numerous national and international diabetes experts and publications in support of her challenge, based on the overwhelming evidence in the

⁵ Contrary to the Secretary's assertion, the claims were not "denied at all levels of the administrative appeals process." In his June 2015 decision, the ALJ explicitly explained why he was not deferring to the Article.

⁶ The Secretary's statement of prior administrative proceedings fails to discuss the favorable ALJ decision that issued in June 2015, wherein the ALJ explicitly explained why he was not deferring to Article when finding for Medicare coverage. The Council reversed the ALJ's decision in November 2015.

administrative record, the ALJ determined a hearing was not necessary. In April 2016, the Civil Remedies Division found:

The contractor and CMS have not produced any record in the form of peer-reviewed literature, medical opinion, or even any analysis from an individual with a medical background that supports a conclusion that CGM is never reasonable and necessary irrespective of the beneficiary's condition. . . . There is simply no evidence before me that explains how CGM does not meet DME requirements or why CGM cannot ever be reasonable and necessary under section 1862(a)(1)(A) of the Act. . . . [T]here are no findings of fact, interpretations of law, and applications of law to fact by the contractor or CMS that are required to be given deference or that may be found reasonable.

See In re: Local Coverage Determination Complaint: Glucose Monitors, HHS Departmental Appeals Board ("DAB") ALJ Decision No. CR4596, 2016 WL 2851236 (April 26, 2016).

Although CMS filed an appeal, based in part on the premise the Medicare beneficiary lost standing to file a challenge when an ALJ declined to follow the Article and deemed Medicare must pay her CGM claims, the relevant DMAC did not appeal the ruling.

B. District Court Rulings and MAC Decisions

Before the Secretary issued the final decisions in this matter, a District Court in Wisconsin ruled that the relevant Article was not entitled to deference when adjudicating claims for CGMs. *See Whitcomb v. Burwell*, CA No. 13-CV-990, 2015 WL 3397697 (E.D. Wis. May 26, 2015). The Secretary did not appeal the ruling. Thus, to the extent the Secretary's decisions denied CGM claims on the basis of the Article, she did so despite the District Court ruling. In May 2016, a second District Court also found that the Article was not entitled to deference. Nonetheless, on August 8, 2016, the MAC issued another decision applying the Article and declining to follow the District Courts' rulings asserting, "we are not bound by the district court's decision in this case. The beneficiary in this case does not reside in the same Federal district as the beneficiary in *Whitcomb*." *See In the case of J.B.*, M-15-907 (Aug. 8, 2016).

Thus, to the extent the MAC relied on the Article in issuing the decisions, the MAC continues to maintain that logic notwithstanding multiple District Court rulings to the contrary.

IV. ARGUMENT

A. The Secretary's Motion Fails to Satisfy the Requirements for a Sixth Sentence Remand

The Secretary's Motion woefully fails to meet any of the requirements of either clause of a 42 C.F.R. § 405(g) sixth sentence remand. With respect to the first clause of a sentence six remand, the Secretary does not make a good cause showing. The Secretary does not admit to legal error, a predicate for "a good cause" showing under the first clause of a sixth sentence remand.⁷ Indeed, her most recent CGM decision indicates she intends to continue to apply the Article despite multiple District Court rulings. Thus, unlike the cases cited in her Motion, the Secretary does not admit error in her decision or analysis. *See* Motion at 8-9.

With respect to the second clause sixth sentence remand, the Secretary does not assert any evidence, let alone what evidence, is missing from the administrative record that warrants a remand. Further, the Secretary does not assert any evidence that will result in a different outcome. Finally, the Secretary cannot satisfy the "good cause" requirement for the failure to include the evidence below despite multiple opportunities to develop the administrative record in support of her denial. CMS, NHIC and the QIC elected not to participate in the ALJ hearing and did not submit any evidence in support of their denials. Indeed, the Secretary simply states "good cause" exists for a remand and the Court should defer to her determination of "good cause." *See* Motion at 8. However, "[t]he Secretary has made no showing that on remand new and material evidence would be introduced. She has not indicated that there is a reasonable possibility that any new evidence would have influenced the Secretary to decide . . . differently.

⁷ The Secretary's citation to "good cause" for sentence four remand cases is inapposite.

And, the Secretary has failed to give any reason, let alone show good cause, why the evidence was not introduced at the prior administrative proceeding. A remand in this case would be contrary to the Congressional policy of encouraging greater care at the administrative level and preventing cases such as this one from going ‘on and on and on.’” *Formica*, 1994 WL 414299, at *2. The Secretary’s desire simply to craft a better or different denial is not a basis for a remand.

B. The MAC’s Decision Cannot Be Cured by a Remand

Unlike the MAC’s other decisions wherein the MAC explicitly stated it was relying on Article A33614,⁸ in the present case the Secretary simply states the MAC *may* have inappropriately given substantial deference to the Article. *See* Motion at 3. Independent of whether the assertion that CGM is “precautionary” appears in an Article that is not entitled to deference as other District Courts have found, the MAC, in rendering the decisions in this case found, although such arguments were not advanced by the MAC or CMS below and are without support in the administrative record, that CGM is precautionary because it does not serve a medical purpose because a “beneficiary must still use another device to accomplish the medical purpose at issue.” Thus, remanding the case back to the MAC will serve no purpose. The MAC’s logic is agnostic as to whether the statement that CGM is precautionary is made in an Article or not – it finds CGM is not used primarily for a medical purpose and is simply precautionary. In view of that finding, the MAC sees no reason to depart from the “guidance” afforded by the Article. In short, unlike other MAC decisions, although the MAC asserted it historically has given deference to Policy Articles,⁹ the MAC did not base its decisions on

⁸ *See Finigan*, M-14-3802 (Medicare Appeal Council, Jan. 20, 2015) (“The Council finds that the record is insufficient to depart from the coverage standards articulated in Local Coverage Article A33614.”); *Whitcomb*, M-13-2509 (Medicare Appeals Council, Aug. 23, 2013) (“The record contains insufficient evidence to support departing from the non-coverage of continuous blood glucose monitor systems, as set forth in local Medicare contractor policies.”).

⁹ *But see In the Case of The Rehabilitation Center, Inc.*, ALJ Appeal No. 1-801426411, M-2012-328 (Medicare Appeals Council, Feb. 24, 2012), where the MAC explicitly acknowledged Articles are not entitled to deference.

deference to the Policy Article. The logic advanced by the MAC was not advanced by those responsible for Medicare policy development, is contrary to Medicare coverage generally, and has been rejected by clinicians and researchers in the field of diabetes.

In either event, in disregarding the District Courts' rulings in *Whitcomb* and *Finigan* on the basis that the Medicare beneficiaries lived in different federal court jurisdictions, the MAC has indicated that it intends to continue to apply the Article when denying claims for Medicare beneficiaries. *See In Re J.B.*, M-15-907 (Medicare Appeals Council, Aug. 8, 2016). Thus, a remand will not "cure" the improper deference to the Article to the extent the decisions rely on it.

C. Dr. Bloom Has Exhausted His Administrative Remedies Repeatedly

1. The Secretary Proposes A Remand Solely to Find a New Basis of Denial

Because Dr. Bloom has a recurring need for supplies for his CGM, Dr. Bloom has taken many cases through the Medicare appeals process, winning some and losing others. The sole basis of denial of these CGM claims was the MAC's determination that CGM is precautionary and therefore excluded from the DME benefit. The MAC articulated no other basis of denial. The MAC's decisions are not supported by the administrative record and, as Dr. Bloom has alleged, is contrary to national and international standards for the management of Type 1 diabetes with hypoglycemic unawareness. It appears the Secretary now seeks a remand in an effort to find a different basis of denial. In either event, the Civil Remedies Division of the Department of Health and Human Services has already found that the assertion that CGM does not fit within the DME statutory benefit is not supported by the administrative record. *See* September 2015 ruling, which was affirmed in April 2016.¹⁰

¹⁰ CMS filed an appeal of the Civil Remedies Division decision arguing, among other points, that the Medicare beneficiary was not an aggrieved party because one of her CGM claims was paid.

2. The Secretary Proposes Remanding Back Multiple Levels to Multiple Different Decision-Makers

Further, because the Secretary seeks to develop new evidence in support of her denial, and new evidence must be developed at the ALJ level where the Medicare beneficiary has an opportunity to respond to it, the Secretary necessarily proposes that the Court remand this matter not one level in the administrative process, but two levels to three different administrative law judges.¹¹ One of the ALJs previously issued a favorable decision finding Medicare must cover Dr. Bloom's CGM and specifically stated his reason for not applying the relevant Article. The MAC reversed the ALJ's decision, ignoring his rationale for not applying the Article while attempting to craft logic to support the statement in the Article. Because the Secretary proposes remanding the case back to three different ALJs, Dr. Bloom would have to endure three more ALJ hearings which may result in three more MAC reviews.

3. The MAC and ALJ Administrative Levels Will Likely Result in a Multi-Year Delay of Resolution

Although statute and regulation require both ALJs and the MAC to render decisions within 90 days of a request for an ALJ hearing or a MAC review, neither is adhering to those timelines. The failure to adhere to the statutory and regulatory timelines has been the subject of multiple class action lawsuits. *See Lessler v. Burwell*, No. 3:14-cv-01230 (D. Conn.) (Filed Aug. 26, 2014) and *American Hosp. Assn v. Burwell*, No. 15-15015 C.A D.C. (Feb. 9, 2016, remanding back to District Court). For 2015, the average time for an administrative law judge to issue a decision on a claim was approximately 547 days and the time period has extended monthly throughout 2016. The Office of Medicare Hearings and Appeals ("OMHA") (which assigns cases to ALJs) is not even opening the mail of individuals seeking an ALJ hearing for 22 weeks, *i.e.*, the requests for an ALJ hearing sit in a mail storage facility in bins without being

¹¹ One MAC decision encompasses two ALJ decisions and the other MAC decision relates to a single ALJ decision.

opened for almost six months. A backlog of over 750,000 ALJ hearing requests exists and is growing. The MAC has indicated that it will take six years to clear its current backlog. *See* hhs.gov/omha/files/Medicare-appeals-backlog.pdf.

Setting aside the failure of ALJs and the MAC to adjudicate cases within the statutory and regulatory timeframes for cases on initial appeal, the MAC and the OMHA have asserted that remanded cases are not subject to the 90-day adjudication period. Thus, remanded cases end up in an endless administrative loop with no temporal relief. The MAC cannot compel ALJs to issue timely decisions and the ALJ is the only level at which testimony may be introduced.¹² The likelihood of all of the ALJs rendering expeditious decisions for a remanded case is vanishingly small.

The Secretary points to the *Finigan* decision in support of her motion for remand. However, the fate of a similar case underscores the futility of the process. First, although the *Finigan* case was remanded to the MAC more than two months ago, the MAC has not remanded the case to an ALJ and thus it languishes at the MAC level un-adjudicated. Second, in May 2015, the Wisconsin District Court remanded the *Whitcomb* case back to the MAC, finding the MAC's application of the Article to be improper. *See Whitcomb*. The case is still languishing at the MAC more than 14 months later.

Further, the Secretary ignores the fact that unlike the other Medicare beneficiaries who have sought relief from District Courts from the Secretary's arbitrary and capricious and unsupported decisions with respect to CGM, Dr. Bloom has secured multiple final favorable decisions through the Medicare appeals process wherein the Medicare adjudicators have found

¹² Although the MAC could conduct hearings and offer oral argument, in view of its tremendous backlog, it repeatedly, publically has stated it will not offer oral argument. *See* <http://www.hhs.gov/omha/OMHA%20Medicare%20Appellant%20Forum/index.html>

that CGM is reasonable and medically necessary for him and is covered by Medicare. Those decisions constitute the Secretary's final decision.

The Secretary suggests that status updates to this Court on the agency's action on the remand is a remedy. However, as the foregoing amply demonstrates, the agency has not accorded the remanded cases any expedited handling and in fact the agency appears to be engaged in a pattern of attempting to avoid judicial oversight of its arbitrary, capricious and unsupported decisions. Reporting the agency's action or inaction provides no remedy to Dr. Bloom.

The dates of service at issue are from March, June and August 2014 – more than two years have passed since Dr. Bloom sought coverage. Two years is longer than any Medicare beneficiary should have to endure for resolution of Medicare coverage of a device and supply that is required to manage a medical condition.

V. CONCLUSION

The Secretary does not make the *prima facie* showing required for a 42 C.F.R. § 405(g) sixth sentence remand. Dr. Bloom, like Sisyphus, repeatedly has exhausted his administrative remedies. The Secretary proposes a remand not to cure an admitted error, but simply to craft additional bases of denial and which will lead to extraordinary delays in resolution – delays which an elderly ill population trying to manage a medical condition can ill endure. For the foregoing reasons, the Defendant's Motion for Remand Pursuant to the Sixth Sentence of 42 U.S.C. §405(g) should be denied.

Dated at Burlington, Vermont this 26th day of August, 2016.

JONATHAN A. BLOOM

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CERTIFICATE OF SERVICE

I, Craig S. Nolan, counsel for Jonathan A. Bloom, do hereby certify that on August 26, 2016, I electronically filed with the Clerk of Court the following document:

**PLAINTIFF'S OPPOSITION TO DEFENDANT'S MOTION FOR REMAND
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Dated at Burlington, Vermont this 26nd day of August, 2016.

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